JAN 1 5 2004

K030267 1/3

VII 510(k) SUMMARY

Date Prepared: 1/24/03
Updated: 10/28/03

Company Name and Address

Aspect Medical Systems, Inc.
141 Needham St.
Newton, MA 02464

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Regulatory Affairs
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Device Name

Proprietary Name: A-2000™ EEG Monitor with BIS.

Common Name: EEG Monitor

Classification

Electroencephalograph (EEG) monitors have been classified by the Neurological Devices Panel as Class II devices (21 CFR 882.1400)

Predicate Devices

Aspect Medical Systems A-2000 EEG Monitor with BIS
This 510(k), #K011534, received FDA clearance 6/15/01

Aspect Medical Systems A-2000 EEG Monitor with BIS
This 510(k), #K031694, received FDA clearance October 10, 2003

Device Description

The Aspect Medical Systems, Inc. EEG BIS Monitor, model A-2000 is an easy to use, microprocessor-based, 2 channel maximum, EEG monitoring system. It monitors the state of the brain by data acquisition of EEG of the anesthetized or sedated patient, as well as monitoring the effects of certain anesthetic agents by use of the processed parameter BIS.

The system configuration consists of the monitor, digital signal converter (DSC), cables, electrodes, and an optional printer.

Intended Use

The Aspect A-2000 EEG Monitor with BIS is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The BIS Monitor is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

Summary of Technological Characteristics Compared to Predicate Device

Similarities

BIS Monitors (predicate and the subject of this 510(k)) are software devices that monitor the state of the brain by data acquisition of EEG of the anesthetized or sedated patient. They also aid in monitoring the effects of certain anesthetic agents by use of the processed parameter BIS.

They have the same hardware and software designs, signal flow, self-test capabilities (automatic and manual), alarms, and identical Digital Signal Converters (DSC).

The system technology remains the same. That is, EEG signals are transformed from analog to digital, processed within the hardware components using similarly designed hardware and software. System self checks and other tests such as impedance checks are still completed, and alarms are similar. None of the differences affect the system technology, or the safety and effectiveness of the BIS Monitor.

Differences

Due to customer request, software is being modified to add Burst Count, which provides a measurement of the number of EEG bursts per minute. Burst count will be added to the BIS log screen.

Software will be updated to revision 1.3.

Summary of Testing

The following tests/analyses have been completed:

1) Software validation
2) Verification of new feature
3) Hazard Analysis and risk assessment

Results indicate the device meets its performance specifications and validation test requirements, and is safe for its intended use.

Conclusion:

Based on the above, Aspect Medical Systems believes the Aspect Medical Systems EEG Monitor with BIS is substantially equivalent to the predicate devices, and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2004

Ms. Christine Vozella
Regulatory Affairs
Aspect Medical Systems, Inc.
141 Needham Street
Newton, Massachusetts 02464

Re: K030267
Trade/Device Name: Aspect A-2000 EEG Monitor with BIS
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: October 28, 2003
Received: October 29, 2003

Dear Ms. Vozella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K030267

Device Name: Aspect Medical Systems A-2000 EEG Monitor with BIS

Indications For Use:

The Aspect A-2000 EEG Monitor with BIS is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The BIS Monitor is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030267